SEP - 7 2004

510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Submitter

Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432

Contact:	Paula Cordero, Regulatory Affairs Specialist
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Date Prepared:	August 10, 2004

Name of Device

Trade Name:	Model 6416 Bipolar Transvenous Temporary Pacing System
Common Name:	Temporary Pacing Lead System
Classification:	Class II

Predicate Devices

The predicate device for the Modified Model 6416 Bipolar Transvenous Temporary Pacing System is the current market released Model 6416 Bipolar Transvenous Temporary Pacing System.

Device Description

The Model 6416 Bipolar Transvenous Temporary Pacing Lead System comprises a temporary lead and a soft-tipped Medtronic guiding catheter. The pacing lead is designed to provide pacing characteristics similar to presently marketed bipolar temporary leads. The lead is introduced percutaneously through the guiding catheter. The lead system is provided in varying lengths to allow for jugular, subclavian, or femoral approach. A removable silicone rubber torque tool is provided on the proximal portion of the lead, to facilitate rotation of the lead during implant and explant. The disposable introducer currently packaged with the system

is the Medtronic Vector X coronary guiding catheter, size 6 French. This catheter guides or steers the temporary lead during placement, and shrouds the active fixation helix from blood vessel walls and other inappropriate tissue until actual implantation in the atrium or ventricle. A hemostasis valve tightens and loosens around the lead and controls the passage of the lead through the guide catheter.

Packaging

The sterile packaging for the Model 6416 Bipolar Transvenous Temporary Pacing System consists of a single pouch configuration. The pouch materials are transparent Tyvek- polyester/polyethylene laminate. The pouches are heat-sealed.

Intended Use

The Model 6416 Bipolar Transvenous Temporary Pacing System features an active fixation, bipolar lead and a soft-tipped lubricated guide catheter. The system is designed for temporary intracardiac pacing and/or EGM recording. The system is disposable, for temporary single patient use with a contemplated implant duration of 7 days or less. The lead and accessories are supplied sterile. The lead is introduced transvenously using the guide catheter. Once within the appropriate chamber, the helical tip electrode of the lead is actively fixed into the endocardium. After lead placement, the guide catheter is removed by sliding it over the lead's bifurcated connector.

Technological Characteristics

The technology used with the Model 6416 Bipolar Transvenous Temporary Pacing System has not changed with the modified Model 6416 Bipolar Transvenous Temporary Pacing System.

Summary of Studies

Medtronic, Inc. performed system compatibility testing to support that the modified Model 6416 Bipolar Transvenous Temporary Pacing System is equivalent to the predicate device. Device testing included:

- Environmental Conditioning
- Visual Verification
- Lead/ Catheter Compatibility testing
- Preclinical confirmation of safety and performance

All system tests performed have demonstrated that the modified Model 6416 Bipolar Transvenous Temporary Pacing System meets the specified requirements.

Sterilization

The Modified Model 6416 Bipolar Transvenous Temporary Pacing System is sterilized using the same100% Ethylene Oxide (EtO) sterilization process as the predicate device. Sterilization certification of the Modified Model 6416 Bipolar Transvenous Temporary Pacing System is based on the manufacturer's determination of substantial equivalence to the predicate device.

Biocompatibility

Biocompatibility testing was not repeated for the modified Model 6416 Bipolar Transvenous Temporary Pacing System. No change was made to material type or material formulation from previously cleared predicate devices.

Conclusion

Through data and information presented, numerous similarities support a determination of substantial equivalence and show the device modification does not affect the intended use of the device or alter the fundamental scientific technology of the device. Market clearance of the Modified Model 6416 Bipolar Transvenous Temporary Pacing System is supported through this Special 510(k) PreMarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Medtronic, Inc.
c/o Ms. Paula Cordero
Regulatory Affairs Specialist
7000 Central Avenue NE
Minneapolis, MN 55432

Re: K042190
Trade Name: Medtronic® Model 6146 Bipolar Transvenous Temporary Pacing System
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent or Temporary Pacemaker Electrode
Regulatory Class: II (two)
Product Code: LDF
Dated: August 10, 2004
Received: August 12, 2004

Dear Ms. Cordero:

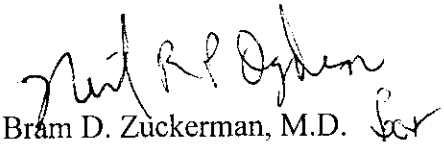
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): N/A K042190

Device Name: Medtronic® Model 6416 Bipolar Transvenous Temporary Pacing System

Indications For Use: The Model 6416 Bipolar Transvenous Temporary Pacing System features an active fixation, bipolar lead and a soft-tipped lubricated guide catheter. The system is designed for temporary intracardiac pacing and/or EGM recording.

The system is disposable, for temporary single patient use with a contemplated implant duration of 7 days or less. The lead and accessories are supplied sterile.

The lead is introduced transvenously using the guide catheter. Once within the appropriate chamber, the helical tip electrode of the lead is actively fixed into the endocardium. After lead placement, the guide catheter is removed by sliding it over the lead's bifurcated connector.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Neil R Ogden

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042190